

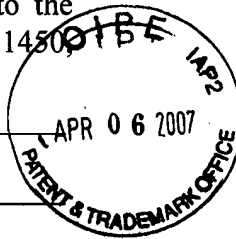
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on April 4, 2007

Glenn P. Ladwig  
Glenn P. Ladwig, Patent Attorney

INFORMATION DISCLOSURE  
STATEMENT

Examining Group 1632  
Patent Application  
Docket No. USF-T192XC1  
Serial No. 10/544,145



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : (Not yet assigned)  
Art Unit : 1632  
Applicant : Shyam S. Mohapatra  
Serial No. : 10/544,145  
Filed : August 2, 2005  
For : Chitosan-Microparticles for IFN Gene Delivery

MS AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, the applicant has not submitted copies of the U.S. patents or published U.S. applications cited on attached Form PTO/SB/08 pursuant to 37 C.F.R. §1.98(a)(2)(ii).

The applicant respectfully asserts that the substantive provisions of 37 C.F.R. §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

Glenn P. Ladwig

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GPL/mv

Attachments: Form PTO/SB/08 (7 pages); copies of some references cited therein



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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				Application Number	10/544,145
				Filing Date	August 2, 2005
				First Named Inventor	Shyam S. Mohapatra
				Art Unit	1632
				Examiner Name	
Sheet	1	of	7	Attorney Docket Number	USF-T192XC1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-6,489,306 B2	12-03-2002	Mohapatra et al.	All
	U2	US-5,527,538	06-18-1996	Baldeschwieler	All
	U3	US-5,441,745	08-15-1995	Presant et al.	All
	U4	US-5,435,989	07-25-1995	Presant et al.	All
	U5	US-5,264,618	11-23-1993	Felgner et al.	All
	U6	US-5,019,369	05-28-1991	Presant et al.	All
	U7	US-4,897,355	01-30-1990	Eppstein et al.	All
	U8	US-2006/0239971 A1	10-26-2006	Mohapatra et al.	
	U9	US-2005/0159385 A1	07-21-2005	Mohapatra	All

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	F1	WO 03/028759 A1	04-10-2003	Univ of South Florida	All	
	F2	WO 02/34287 A2	05-02-2002	Pharmexa A/S	All	
	F3	WO 99/36089 A1	07-22-1999	Johns Hopkins Univ	All	
	F4	WO 97/45442 A1	12-04-1997	Imperial College Sci Tech Med.	All	
	F5	WO 97/20576 A1	06-12-1997	Danbiosyst UK Lmted	All	
	F6	WO 95/02698 A1	01-26-1995	Life Tech., Inc.	All	
	F7	WO 91/15501 A1	10-17-1991	Yale University	All	

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	U10	US-2005/0266093 A1	12-01-2005	Mohapatra	All
	U11	US-2005/0158327 A1	07-21-2005	Mohapatra et al.	All
	U12	US-2004/0175384 A1	09-09-2004	Mohapatra et al.	All
	U13	US-2004/0009152 A1	01-15-2004	Mohapatra et al.	All
	U14	US-2003/0198624 A1	10-23-2003	Mohapatra et al.	All
	U15	US-2003/0068333 A1	04-10-2003	Mohapatra et al.	All
	U16	US-10/655,873	09-05-2003	Mohapatra et al. (patent application)	All
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	R1	Accession No: NM_000639, NCBI database, "Homo sapiens Fas ligand (TNF superfamily, member 6) (FASLG), mRNA" August 1, 2005.	
	R2	BEHERA, A.K. <i>et al.</i> "2'-5' oligoadenylate synthetase plays a critical role in interferon- $\gamma$ inhibition of respiratory syncytial virus infection of human epithelial cells" <i>J Biol Chem</i> , 2002, 277:25601-25608.	
	R3	BEHERA, A.K. <i>et al.</i> "Adenovirus-mediated interferon $\gamma$ gene therapy for allergic asthma: involvement of interleukin 12 and STAT4 signaling" <i>Human Gene Therapy</i> , 2002, 1697-1709.	
	R4	BIVAS-BENITA, M. <i>et al.</i> "Pulmonary delivery of chitosan-DNA nanoparticles enhances the immunogenicity of a DNA vaccine encoding HLA-A*0201-restricted T-cell epitopes of <i>Mycobacterium tuberculosis</i> " <i>Vaccine</i> , 2004, 22:1609-1615.	
	R5	BORASCHI, D. <i>et al.</i> "Interferons inhibit LTC <sub>4</sub> production in murine macrophages" <i>J Immunol</i> , 1987, 138:4341-4346.	
	R6	BROOKING, J. <i>et al.</i> "Transport of nanoparticles across the rat nasal mucosa" <i>J Drug Target</i> , 2001, 9:267-279.	
	R7	DAINES, M.O. and HERSHEY, G.K. "A novel mechanism by which interferon- $\gamma$ can regulate interleukin (IL)-13 responses" <i>J Biol Chem</i> , 2002, 277(12):10387-10393.	
	R8	DE SMEDT, S.C. <i>et al.</i> "Cationic polymer based gene delivery systems" <i>Pharm. Res.</i> , 2000, 17:113-126.	
	R9	DOW, S.W. <i>et al.</i> "Systemic and local interferon $\gamma$ gene delivery to the lungs for treatment of allergen-induced airway hyperresponsiveness in mice" <i>Hum Gene Ther</i> , 1999, 10:1905-1914.	
	R10	ERBACHER, P. <i>et al.</i> "Chitosan-based vector/DNA complexes for gene delivery: biophysical characteristics and transfection ability" <i>Pharm Res</i> , 1998, 15:1332-1339.	
	R11	FILIPOVIĆ-GRČIĆ, J. <i>et al.</i> "Mucoadhesive chitosan-coated liposomes: characteristics and stability" <i>J Microencapsul</i> , 2001, 18:3-12.	
	R12	FLAISHON, L. <i>et al.</i> "Cutting edge: Anti-inflammatory properties of low levels of IFN- $\gamma$ " <i>J Immunol</i> , 2002, 168:3707-3711.	
	R13	FORD, J.G. <i>et al.</i> "IL-13 and IFN- $\gamma$ : interactions in lung inflammation" <i>J Immunol</i> , 2001, 167:1769-1777.	

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	R14	GARNETT, M.C. "Gene-delivery systems using cationic polymers" <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 1999, 16:147-207.	
	R15	GURUJEYALAKSHMI, G. and GIRI, S.N. "Molecular mechanisms of antifibrotic effect of interferon gamma in bleomycin-mouse model of lung fibrosis: Downregulation of TGF- $\beta$ and procollagen I and III gene expression" <i>Exp Lung Res</i> , 1995, 21:791-808.	
	R16	HAMAJIMA, K. <i>et al.</i> "Chitin micro-particles (CMP): A useful adjuvant for inducing viral specific immunity when delivered intranasally with an HIV-DNA vaccine" <i>Viral Immunology</i> , 2003, 16:541-547.	
	R17	HAYES, M.P. <i>et al.</i> "Regulation of interleukin-12 expression in human monocytes: Selective priming by interferon- $\gamma$ of lipopolysaccharide-inducible p35 and p40 genes" <i>Blood</i> , 1995, 86:646-650.	
	R18	HELLERMAN, G. <i>et al.</i> "Chitosan IFN-gamma-gene nanosphere (CIN) therapy for allergic asthma: Modulation of specific T-cell and dendritic cell responses" <i>J. Allergy Clin Immunol.</i> , 2003, 111:S265, abstract no. 791.	
	R19	HELLERMANN, G.R. <i>et al.</i> "Mechanism of cigarette smoke condensate-induced acute inflammatory response in human bronchial epithelial cells" <i>Resp. Res.</i> , 2002, 3:22-30.	
	R20	KABANOV, A.V. "Taking polycation gene delivery systems from <i>in vitro</i> to <i>in vivo</i> " <i>Pharm.Sci.Tech.Today</i> , 1999, 2:365-372.	
	R21	KIM, Y.H. <i>et al.</i> "Structural characteristics of size-controlled self-aggregates of deoxycholic acid-modified chitosan and their application as a DNA delivery carrier" <i>Bioconj Chem</i> , 2001, 12:932-938.	
	R22	KOLTOVER, I. <i>et al.</i> "An inverted hexagonal phase of cationic liposome-DNA complexes related to DNA release and delivery" <i>Science</i> , 1998, 281:78-81.	
	R23	KONG, X. <i>et al.</i> "Chitosan IFN-gamma-gene nanoparticle (CIN) therapy for allergic asthma in mice involves STAT4 signaling pathway" <i>J. Allergy Clin Immunol.</i> , 2003, 111:S354, abstract no. 1144.	
	R24	KOTZÉ, A.F. <i>et al.</i> "Enhancement of paracellular drug transport with highly quaternized N-trimethyl chitosan chloride in neutral environments: In vitro evaluation in intestinal epithelial cells (Caco-2)" <i>J Pharm Sci</i> , 1999, 88:253-257.	
	R25	KRASNOWSKA, M. <i>et al.</i> "Effect of recombinant IFN- $\gamma$ on IgE-dependent leukotriene generation by peripheral blood leukocytes in patients with pollinosis and asthma" <i>Arch Immunol Ther Exp (Warsz)</i> , 2000, 48:287-292.	
	R26	KUMAR, M. <i>et al.</i> "Role of mucosal IFN- $\gamma$ gene transfer on allergic sensitization and RSV infection" <i>J. Allergy Clin Immunol.</i> , 2002, 109:S4, abstract no. 78.	

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	R27	KUMAR, M. <i>et al.</i> "Intranasal gene transfer by chitosan-DNA nanospheres protects BALB/c mice against acute respiratory syncytial virus infection" <i>Human Gene Therapy</i> , 2002, 13:1415-1425.	
	R28	KUMAR, M. <i>et al.</i> "IFN- $\gamma$ and IL-12 plasmid DNAs as vaccine adjuvant in a murine model of grass allergy" <i>J Allergy Clin Immunol</i> , 2001, 108:402-408.	
	R29	KUMAR, M. <i>et al.</i> "Intranasal IFN- $\gamma$ gene transfer protects BALB/c mice against respiratory syncytial virus infection" <i>Vaccine</i> , 1999, 18:558-567.	
	R30	LI, X-M. <i>et al.</i> "Mucosal IFN- $\gamma$ gene transfer inhibits pulmonary allergic responses in mice" <i>J Immunol</i> , 1996, 157:3216-3219.	
	R31	MATSUSE, H. <i>et al.</i> "Recurrent respiratory syncytial virus infections in allergen-sensitized mice lead to persistent airway inflammation and hyperresponsiveness" <i>J Immunol</i> , 2000, 164:6583-6592.	
	R32	MINAGAWA, K. <i>et al.</i> "Direct observation of the biphasic conformational change of DNA induced by cationic polymers" <i>FEBS Lett.</i> , 1991, 295:67-69.	
	R33	MINSHALL, E. <i>et al.</i> "Eosinophil-associated TGF- $\beta_1$ mRNA expression and airways fibrosis in bronchial asthma" <i>Am J Respir Cell Mol Biol</i> , 1997, 17:326-333.	
	R34	MIYAZAKI, S. <i>et al.</i> "Chitosan and sodium alginate based bioadhesive tablets for intraoral drug delivery" <i>Biol. Pharm. Bull.</i> , 1994, 17(5):745-747.	
	R35	MOSMANN, T.R. <i>et al.</i> "TH1 and TH2 cells: Different patterns of lymphokine secretion lead to different functional properties" <i>Ann Rev Immunol</i> , 1989, 7:145-173.	
	R36	MURRAY, H.W. "Current and future clinical applications of interferon-gamma in host antimicrobial defense" <i>Intensive Care Med</i> , 1996, 22(Suppl 4):S456-S461.	
	R37	MUZZARELLI, R. <i>et al.</i> "Reconstruction of parodontal tissue with chitosan" <i>Biomaterials</i> , 1989, 10:598-603.	
	R38	NISHIMURA, K. <i>et al.</i> "Immunological activity of chitin and its derivatives" <i>Vaccine</i> , 1984, 2:93-99.	
	R39	OTTERLEI, M. <i>et al.</i> "Characterization of binding and TNF- $\alpha$ -inducing ability of chitosans on monocytes: the involvement of CD14" <i>Vaccine</i> , 1994, 12:825-832.	

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	R40	PAPINEAU, A.M. <i>et al.</i> "Antimicrobial effect of water-soluble chitosans with high hydrostatic pressure" <i>Food Biotechnol</i> , 1991, 5:45-57.	
	R41	PIERKES, M. <i>et al.</i> "Decreased release of histamine and sulfidoleukotrienes by human peripheral blood leukocytes after wasp venom immunotherapy is partially due to induction of IL-10 and IFN- $\gamma$ production of T cells" <i>J Allergy Clin Immunol</i> , 1999, 103:326-332.	
	R42	REMY, J-S. <i>et al.</i> "Gene transfer with lipospermines and polyethylenimines" <i>Adv. Drug Deliv. Rev.</i> , 1998, 30:85-95.	
	R43	RICHARDSON, S.C. <i>et al.</i> "Potential of low molecular mass chitosan as a DNA delivery system: biocompatibility, body distribution and ability to complex and protect DNA" <i>Int. J. Pharm.</i> , 1999, 178:231-243.	
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	R50	WROBEL, I. and COLLINS, D. "Fusion of cationic liposomes with mammalian cells occurs after endocytosis" <i>Biochem. Biophys. Acta</i> , 1995, 1235:296-304.	
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/544,145	
			Filing Date	August 2, 2005	
			First Named Inventor	Shyam S. Mohapatra	
			Group Art Unit	1632	
			Examiner Name		
			Attorney Docket Number	USF-T192XC1	
Sheet	7	of	7		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R53	PERRICONE, M.A. <i>et al.</i> "Aerosol and lobar administration of a recombinant adenovirus to individuals with cystic fibrosis. II. Transfection efficiency in airway epithelium" <i>Human Gene Therapy</i> , 2001, 12:1383-1394.	
	R54	"Gene" from The American Heritage Dictionary of the English Language, 4 <sup>th</sup> Ed. (online), 2000 (retrieved on 2006-06-15). Retrieved from the Internet: <URL: <a href="http://dictionary.reference.com/browse/gene">http://dictionary.reference.com/browse/gene</a> >.	
	R55	"Timolol Maleate" from RxList The Internet Drug Index (online), 2006 (retrieved on 2006-06-15). Retrieved from the Internet: <URL: <a href="http://www.rxlist.com/cgi/generic3/timololgfs_wcp.htm">http://www.rxlist.com/cgi/generic3/timololgfs_wcp.htm</a> >.	
	R56	"Respiratory tract" from Wikipedia (online), 2006 (retrieved on 2006-06-15). Retrieved from the Internet: <URL: <a href="http://en.wikipedia.org/wiki/Respiratory_tract">http://en.wikipedia.org/wiki/Respiratory_tract</a> >.	
	R57	RENER, X. <i>et al.</i> "Construction and identification of a recombinant adenovirus which expresses human interferon- $\gamma$ " <i>Chinese J. Biotech.</i> , 1997, 13:1-8.	
	R58	FLOTTE, T. and LAUBE, B. "Gene therapy in cystic fibrosis" <i>Chest</i> , 2001, 120:124S-131S.	
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